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APR - 2 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 1900 hGH IRMA Kit
Classification Name: Immunoradiometric Assay for hGH
Analyte Code and Name: hGH
Regulatory Class: I

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Date: February 25, 1997

The DSL hGH IRMA kit was developed for the quantitative measurement of hGH in human serum. The IRMA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the coated tube, the other antibody is radiolabelled for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed by decanting and washing the tube. The resultant is analyzed in a gamma counter for net counts. The amount of bound hGH is directly proportional to the concentration of the hGH present in the sample.

The DSL hGH IRMA assay is intended for the quantitative determination of hGH in human serum. The measurement of hGH is used as a diagnostic aid in the evaluation of hGH deficiency disorders or acromegaly.

The DSL 1900 hGH IRMA is substantially equivalent to the DSL 10-1900 hGH ELISA.

To demonstrate substantial equivalence between the two assays, human serum samples (n=68) were collected and assayed using both methods. Samples were chosen based on expected hGH levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation $Y = 0.93(\text{DSL 10-1900}) - 0.19$ with a correlation coefficient of $(r) = 0.97$.